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Remarks

Claims 14-30 and 37-39 are under consideration.

Claims 19, 24 and 27 are amended to further define the present invention. The current amendments to claims 19, 24 and 27 underscore the fact that the claimed beads have a surface coating which is a silver nitrate composition.

Claims 38 and 39 are new, and are directed to the embodiments exemplified in Examples 1 and 2.

The rejection of claims 19, 20, 24, 25, 26, 28, 30 and 37 under 35 U.S.C. §102(b) as anticipated by Tsukisaka et al. is not warranted, and is hereby traversed.

The present claims define a delivery vehicle for medical use and call for physiologically inert beads that carry a coating which is a silver nitrate composition.

The antibiotic beads shown by Tsukisaka et al. clearly are not physiologically inert and are not intended for an invasive medical use. The English language Abstract of Tsukisaka et al. does not teach a physiologically inert bead coated with a silver nitrate composition and suitable for treatment of menorrhagia. To the contrary, the binder for the particulate matter that makes up the bead is distributed on the surface of the antibiotic bead. The binder consists of an antibiotic metal salt of organic polymer (Abstract). Even when the antibiotic metal is silver, the antibiotic metal salt of organic polymer is water insoluble (machine translation [0009]) is not silver nitrate and cannot be silver nitrate, a water soluble inorganic salt.

There is also no valid basis for the Examiner's "interpretation" that the porous antibiotic bead is suitable for physiological use. There is no teaching of record that sanitary goods can be introduced beneficially into the uterine cavity.

There is also no teaching in the Abstract that the antibiotic beads provide a coating with a tissue necrosing amount of a silver nitrate composition. Sanitary goods, if intended for skin contact, most certainly would not contain a tissue necrosing amount of any antibiotic. An antibiotic is used to kill microorganisms, not to necrose tissue. It is also noted that the machine translation of Tsukisaka et al. does not use the term "antibiotic" but instead uses the terms "antibacterial" and "antimicrobial", neither of which suggests tissue necrosis.

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If the rejection of present claims based on JP 05345010 A is maintained, applicant hereby requests an accurate translation of this particular reference.

It is not clear from the Office Action whether the current anticipation rejection is based on the Abstract or on the undated machine translation of JP 05345010 A. This undated machine translation is not a proper reference against the claims in any event.

The Examiner's statement that the bead "can contain ... silver nitrate" is not supported by the Abstract or the machine translation. Paragraphs [0013] and [0014] refer to starting materials only. Even if silver nitrate were to be the starting material, it is converted to a silver salt of an organic polymer that has antibacterial activity [0008], [0009]. There can be no silver nitrate on the surface of the antibiotic bead – if silver nitrate was the starting material it was converted to a silver salt of an organic polymer as the bead was formed.

The fact that a binder such as alginic acid, CMC, polystyrene sulphonate, polyacrylate, etc., may be physiologically tolerable is of no moment. The present claims call for the bead itself to be physiologically inert. Here neither the Abstract nor the undated machine translation anticipate any of the rejected claims.

As to the intended medical use, it does indeed impose a structural difference between the claimed article of manufacture and the prior art antibiotic bead made up of particulate matter. Specifically, in the claimed article of manufacture a physiologically inert bead is the carrier of the tissue necrosing composition whereas the antibiotic bead described in the applied reference is not and cannot possibly be physiologically inert, and also does not have a surface coating that necroses tissue.

The anticipation rejection of claims 19, 20, 24, 25, 26, 28, 30 and 37 is not well taken for any one of the foregoing reasons and should be withdrawn.

Newly presented claims 38 and 39 are likewise not anticipated by the Abstract or the machine translation for the same reasons as set forth hereinabove.

The rejection of claims 14-30 and 37 under 35 U.S.C. §103(a) as unpatentable over Tsukisaka et al. (JP 05345010 A) in view of Neuwirth (WO 96/40171), Block, Hirai et al. (U.S. Patent No. 5,213,895) and Siiman et al. (U.S. Patent No. 5,552,086) is traversed as well.

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Scope and Content of the Prior Art

The present claims define a delivery vehicle for a specific, invasive therapeutic use. Only one of the applied references (Neuwirth) pertains to a therapeutic use of any kind. The rest of the references thus have been selected from non-analogous art.

The shortcomings of Tsukisaka et al. as a reference, discussed in detail hereinabove, are not cured by any of the cited secondary references. Before addressing the attempted combination of references, it must be re-iterated that Tsukisaka et al. does not teach that the antibiotic bead described therein can contain a silver nitrate. See, for example, the machine translation at [0022]. Tsukisaka et al. also does not teach that styrene beads and polyethylene beads of the size presently claimed can be used. Tsukisaka et al. machine translation at [0016], [0017] and [0018] clearly describes only fine particles of styrene and of a polyester that can be used, together with a binder and the antibacterial metal salt of an organic polymer to make the antibiotic bead. There is no teaching or suggestion that these fine styrene or polyester particles are porous.

The Secondary References Are Not Combinable With the Primary Reference

Applicant's own publication, WO 96/40171, is inapposite inasmuch as it only teaches the use of silver nitrate together with dextran paste, and the like. The caustic properties of silver nitrate are not in issue here. It is significant, however, that Tsukisaka et al. expressly teach that silver nitrate must be converted to a salt of an organic polymer in bead form. Such a teaching clearly militates against the use of silver nitrate per se in the antibiotic beads of Tsukisaka et al.

Likewise, and for the same reason, one of ordinary skill would not have even attempted to use the toughened silver nitrate described by Block when making the antibiotic beads. The necrosing effect of silver nitrate is well known. This is why one of ordinary skill would have avoided the use of silver nitrate in antibiotic beads that may be used in sanitary goods that could come in contact with tissue. The teachings of Block are not combinable with those of Tsukisaka et al. One of ordinary skill in the medical field would not have done so.

Hirai et al. describes a metal particle bearing composite that has excellent catalytic properties. This composite may contain silver metal, but does not contain a silver ion releasing compound. Example 15 of Hirai et al. shows the reduction of silver nitrate to

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metallic silver. See, for example, col. 17, line 46. Tsukisaka et al. seeks to form a silver salt of an organic polymer. The metal containing composite of Hirai et al. simply is not suitable for that purpose. The teachings of Hirai et al. are not combinable with those of the primary reference. The Examiner has not advanced a single valid reason why one would have done so.

Siiman et al. describes inter alia, colloidal polymeric particles (0.5 to 5 microns in size) coated with metallic silver.

Example 6, however, describes the formation of metallic palladium particles, not silver (col. 12, lines 21, 32). Example 9 describes the formation of metallic gold particles, not silver (col. 13, lines 29, 43).

This reference also is not combinable with Tsukisaka et al. because the silver carried on these colloidal particles will not produce the salt of an organic polymer sought by Tsukisaka et al. The teachings of Siiman et al. are not combinable with those of the principal reference.

Hirai et al. and Siiman et al. both describe a product that contains metal, not a silver salt, thus the respective products are not silver ion releasing compounds. Hirai et al. as well as Siiman et al. are outside of the proper scope of relevant art vis-a-vis Tsukisaka et al., have been selected from non-analogous art with impermissible reliance upon Applicant's own specification for guidance, and cannot be combined with Tsukisaka et al. to support an obviousness rejection.

Differences Between Prior Art and Claims

Applicant concurs with the five differences noted by the Examiner between the principal reference, Tsukisaka et al. and the claims. In addition, Tsukisaka et al. fail to teach the following additional material differences:

- A. A delivery vehicle suitable for use in the treatment of menorrhagia is not shown by Tsukisaka et al.
- B. Physiologically inert, separate beads are not shown by Tsukisaka et al.
- C. A tissue necrosing amount of a water-soluble silver ion releasing compound coated on the surface of each physiologically inert bead is not taught by Tsukisaka et al.

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Prima Facie Obviousness Has Not Been Established

1. Without resort to the Applicant's own teachings, there is no apparent reason to combine the references as the Examiner has done.

2. Tsukisaka et al. expressly teaches the formation of a bead for non-therapeutic uses that contains an antibacterial metal salt of an organic polymer which is water insoluble. Accordingly, silver perchlorate, silver permanganate, silver acetate and silver lactate monohydrate are expressly excluded from the teaching. Neuwirth does not teach the purported equivalence. Neuwirth does not even mention antibiotics.

3. There is no evidence of record as to the level of skill possessed by one of ordinary skill in the pertinent art, yet it is the Examiner's onus to do so. Unless this level of skill has been resolved, there can be no meaningful evaluation of obviousness.

4. As to the addition of up to about 5% potassium citrate, Tsukisaka et al. teachings are expressly limited to silver, copper and zinc, and thus exclude potassium nitrate. The teachings of Block are inapposite for reasons advanced hereinabove. There is no apparent reason why Tsukisaka et al. would even want to use "toughened silver nitrate."

5. As to the specifically claimed ranges of silver nitrate, nothing in Tsukisaka et al. would have led to the claimed ranges. Tsukisaka et al. utilizes silver nitrate only as a starting material to make the corresponding salt of an organic polymer in order to achieve an extended antimicrobial effect. See machine translation [0025]. Furthermore, a determination of desirable amounts for antimicrobial activity as in Tsukisaka et al., does not provide any guidance to anyone as to tissue necrosing amounts. The Examiner's own, unsupported testimony of what would have been obvious to one of ordinary skill is of no moment, and cannot support a rejection of the claims.

6. Regarding the presence of a polysaccharide binder, no such binder is taught by the primary reference. Tsukisaka et al. use a binder such as rubber, plastic, or paper to shape and form the antibiotic bead, and to retain the silver organic polymer salt within the frame of the formed bead. The present claims define an article of manufacture that includes a physiologically inert bead having only a surface coating that contains silver nitrate. The teachings of Siiman et al. do not bridge this gap because Siiman et al. deal only with metal particles, not metal ions.

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7. A binder matrix for colloidal metal particles that are to be retained within the binder is not necessarily a suitable binder for the considerably larger antibiotic beads of Tsukisaka et al. There has been no showing why one of ordinary skill would have turned to Siiman et al. when seeking to improve the antibiotic bead of Tsukisaka et al., which bead is made of powdery substance such as calcium phosphate, talc, mica, peolite, and the like materials. See Abstract. The binders mentioned by Tsukisaka et al. are rubber, plastics and paper (machine translation [0006]). No equivalence has been shown for the aminodextran of Siiman et al. with the foregoing binders. Alginic acid, CMC, polystyrene sulphonate, polyacrylate, etc., are taught as organic polymers, not binders.

8. Regarding polyvinylpyrrolidone (PVP) as a binder for the antibiotic beads of Tsukisaka et al., as noted hereinabove Hirai et al. produce catalytic metal particles, not metal salts of organic polymers. One of ordinary skill would not have had any reason to turn to Hirai et al. when seeking to improve on rubber, plastics or paper as a binder for the antibiotic beads of Tsukisaka et al. for the simple reason that Hirai et al. do not use PVP as a binder but as a protective polymer adsorbed on individual colloidal metal particles.

9. Even if, *arguendo*, the combinations of reference teachings alluded to by the Examiner were implemented, such combinations would not have produced the claimed invention. None of these combinations result in a delivery vehicle for a silver ion releasing compound, such as silver nitrate, suitable for use in treating menorrhagia, and none of these combinations result in a delivery vehicle that has physiologically inert beads that carry a water-soluble silver ion releasing compound coated on their surface in a tissue necrosing amount. There can be no reasonable expectation of success to produce a delivery vehicle suitable for the treatment of menorrhagia when neither the primary reference nor the secondary references even mention such treatment.

10. The very recent U.S. Supreme Court decision in KSR International Co. v. Teleflex, Inc., No. 04-1350 (U.S., April 30, 2007) is instructive on the issue of obviousness. The Court cited with approval In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006):

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

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This standard for an obviousness rejection has not been met in this case. The stated Rational (*sic*) and Motivation (MPEP 2142-2143) lacks citations to the references, and is replete with conclusory statements and generalizations not supported by the applied references. The conclusion is inescapable that the Examiner has impermissibly substituted his own expertise in rejecting the claims, rather than basing the rejection on the reference of record. Withdrawal of the obviousness rejection is earnestly urged.

Early passing of this application to issue is solicited.

Respectfully submitted,

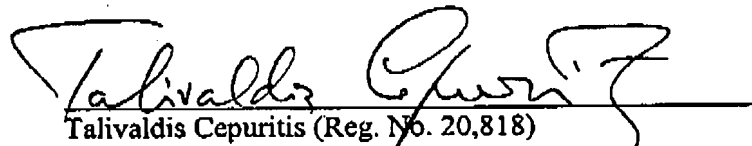
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